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IN UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Michael Douglas Spears, M.S.

Filed: 28 February 2002

Serial No: 10/070,342

Confirm No: 2921

Docket: SPER -100A

For: Tool and Method for Cutting Powered by an Electromagnetic (EM) Source

Examiner: A. F. Roane
Group Art: 3739

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ATTACHMENT to the Amendments/RCE

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Date of Transmission: 22 th day of January, 2004
By: Jean M Macheledt (printed name)

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Dear Sir:

I, Bruce Lanier Walcott, a citizen of the United States of America, hereby declare and state:

THAT I am familiar with the handheld-sized probe for cutting and cauterizing tissue pictured and explained by Mr. Michael Spears in his published US patent application entitled "*Tool and Method for Cutting Powered by an Electromagnetic (EM) Source*", No. 10/070,342—a copy of which I've seen.

THAT I am a professor of electrical engineering having received my doctorate of philosophy degree from Purdue University with a specialty and focus in electrical engineering.

THAT I have a thorough understanding of the theoretical methods used in the hand-held probe.

THAT I am not an inventor of the technology covered by the patent application currently being examined; and I am not an employee or consultant affiliated with the inventor, Michael Spears.

THAT I have read the description and figures depicted on the next pages as well as the related description of the Yamanashi Patent No. 6,059,781 (known as the "later" Yamanashi patent) and the earlier Yamanashi patent No. 5,019,076 with the foot pedal design; I have also reviewed the details of the figures and associated description to Esty, Patent No. 4,032,738 shown also on the following pages. The two Yamanashi patents and the Esty patent depict traditional designs for devices used to cut and cauterize tissue in that the switch mechanisms for the devices are located far the probe, itself. Mr. Spears' patent application design, however, has the switch located on the probe body where it is far more convenient for the user to activate. Thus, none of the three designs shown in the subsequent pages are similar to Mr. Spears' design.

THAT in his published patent application Mr. Spears discusses the design of the earlier Yamanashi patent, stating:

> Known early-generation surgical tools include the electromagnetic field focusing (EFF) probe and the later-developed electroconvergent cautery (ECC) system, both of which include a system of large, complex external subassemblies; for reference, see FIG. 1 which is a block diagram illustrating the current EFF system setup; and for the ECC system setup, see Patil, A.A., Yamanashi, W.S. "Electroconvergent Cautery" ***Neurosurgery***, Vol. 35, No. 4 (October 1944): 785-788. In either case, the handheld probes associated with the EFF or ECC systems (in FIG. 1, EFF probe is labeled **P**) merely include a hot tip for cutting, wiring that extends the length of the probe handle, a vacuum tube attached to an external vacuum source to aid in the removal of vaporized tissue and fluids generated at the hot tip of the probe during operation, and an electrical connector at the other end of the probe handle for connecting to the external, complex impedance matching assembly (such as that represented in FIG. 1 and labeled **IMN**). A separate probe ON/OFF foot pedal, labeled **FP** in FIG. 1, is electrically hardwired to the probe system for use by a surgeon. Unfortunately, the foot pedal switch and the separate probe tuner of the known system are awkward—taking up much-coveted space in an operating room. Furthermore, not only is it difficult for a surgeon to locate, without the benefit of direct visual aids, the foot pedal of these prior devices while concentrating on handling and focusing the probe to cut the necessary area of tissue, but once the foot pedal is located, a surgeon's foot can ~~accidently~~ accidentally fall-off of the pedal– which of course can create very dangerous situations during surgery causing inadvertent injury [*as corrected*].
>
> Unlike these known proposed cutting systems, one can readily appreciate the efficient, streamlined design of the handy novel tool and method for cutting of the invention. It is important to note that the new tool preferably has a switch incorporated with a handheld-sized probe housing, as well as impedance matching circuitry encased within the probe housing to help transform load impedance into

the characteristic impedance of the input RF power to obtain maximum power transfer (impedance matching) and improve coupling efficiency of the tool network, all of which make the new tool more convenient to a user. ...

Yamanashi

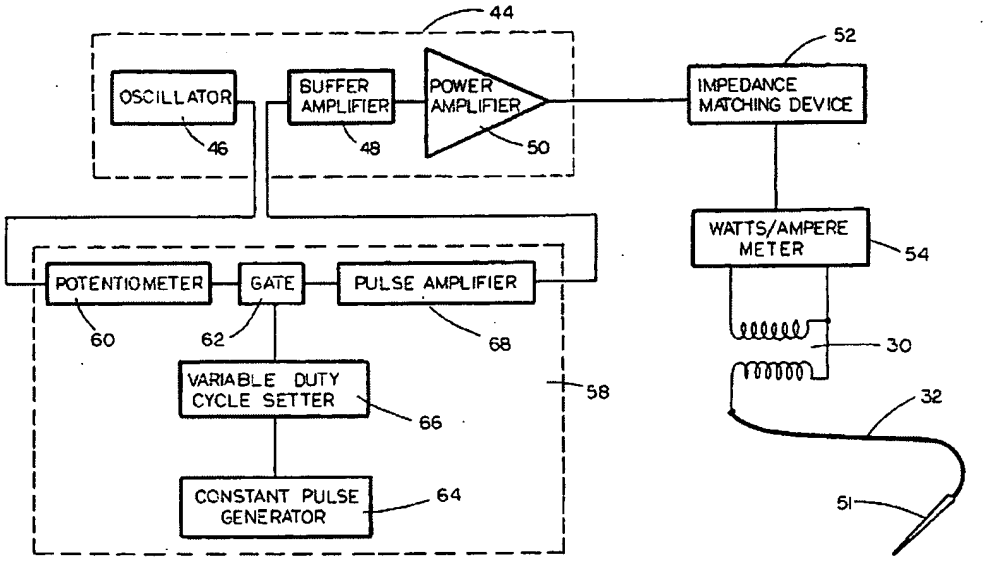


FIG. 6

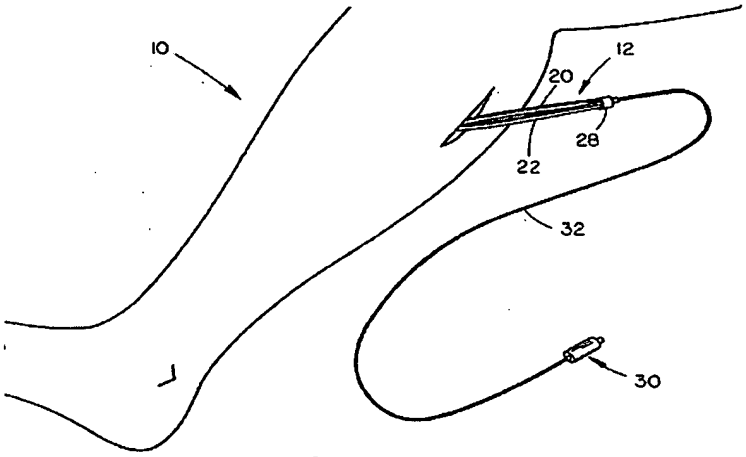


FIG. 1

See next page for discussion

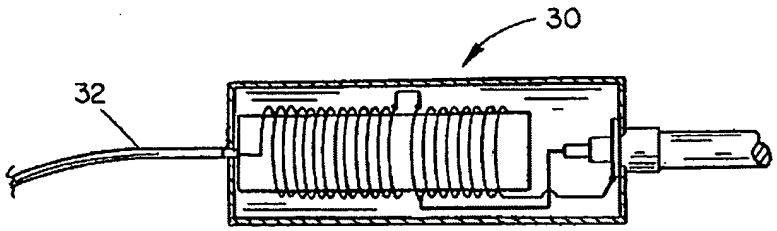


FIG. 7

The surgical forceps **12** illustrated in FIG. **2** comprises a pair of straight blades **20** and **22** which are insulated except for the tips **24** and **26**. Blades **20** and **22** are separated at their proximal ends by a heavily insulated material referred to generally by the reference numeral **28**. Blade **20** serves as the active blade and is connected to the loading and tuning coil **30** by means of a heavily insulated cable **32**. Blade **22** is passive and has no electrical connections. As seen in FIG. **2**, blades **20** and **22** taper towards their sharply pointed tips. Tip **24** of blade **20** is approximately 0.25 mm longer than the tip of the passive blade **22**.

With respect to FIG. **3**, the surgical forceps **14** illustrated therein are generally similar to the forceps shown in FIG. **2** except that the blades **34** and **36** are bayonetted. Blade **34** is the active blade and is electrically connected to the insulated cable **32**. As in the surgical forceps **12**, the tips of the active blade **34** is approximately 0.25 mm longer than that of the tip of the blade **36**.

FIG. **4** illustrates a laparoscopic forceps which is similar to the surgical forceps of FIGS. **2** and **3** above except that the blades **38** and **40** are short with the main stems thereof being quite long. Blade **38** is operatively connected to the insulated cable **32**.

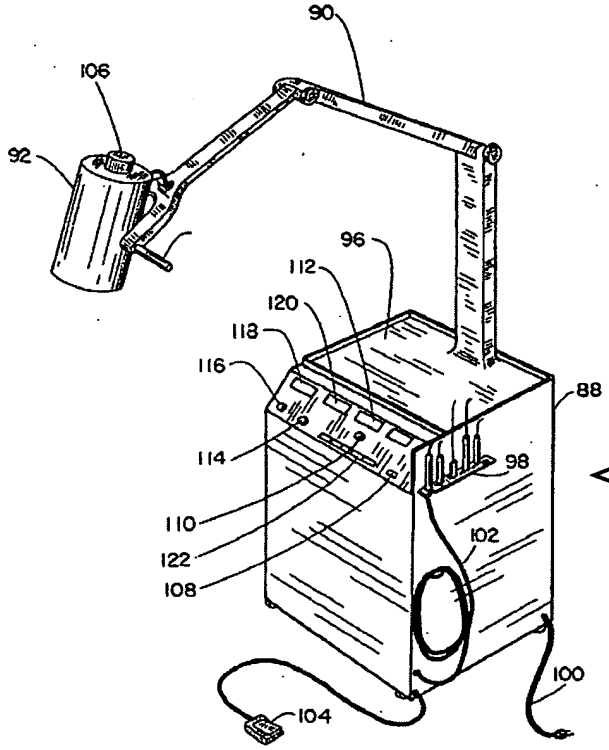
The surgical probe **18** illustrated in FIG. **5** comprises a rigid wire **42** with a tapered fine tip **43**. Except for approximately 5 mm of the tip **43**, the remainder of the probe is insulated in pencil shaped configuration for gripping purposes.

An endoscopic probe may also be provided which is generally similar to the surgical probe **18** of FIG. **5** except that the tip portion thereof may be straight, curved or angled. The outer diameter of the probe would be approximately 0.75 to 2 mm. The length of the probe would be a multiple of **22** and may be rigid or flexible. This probe may be used as a resectoscope or as an endovascular probe. Further, the probe could have its tip bent at a right angle.

The cautery instruments of FIGS. **2**, **3**, **4** and **5** are to be utilized with electrical circuitry illustrated in FIG. **6** and **7**. Inasmuch as many of the components of that shown in FIG. **6** are identical or similar to that taught in U.S. Pat. No. 5,019,076, reliance upon said patent is made to complete this disclosure, if necessary. In other words, the parameters or specifications of the various components of FIG. **6** will not be described since it is believed that the same are disclosed in U.S. Pat. No. 5,019,076 or would be obvious to one having ordinary skill in the art.

See next page for No. 5,019,078

The numeral **44** refers to a radio frequency power generator comprises an oscillator **46**, buffer amplifier **48** and power amplifier **50**. As seen in FIG. **6**, an impedance matching device **52** is electrically connected to the radio frequency power generator. A watts/ampere meter **54** is electrically connected to the impedance matching device **52** and is electrically connected to the loading and tuning coil **30**. Loading and tuning coil **30** is connected to the surgical instrument SI by means of the heavily insulated cable **32**. As stated, the surgical instrument SI may be comprised of those instruments previously described. The cable **32** connects the surgical instrument SI to the loading and tuning coil **30** as described and would have a length of 110 centimeters or a multiple of **22**.



This is the earlier Yamanashi design referenced in the later Yamanashi patent.

Only shows a foot pedal switch.

probes connected with cable

Fig. 9

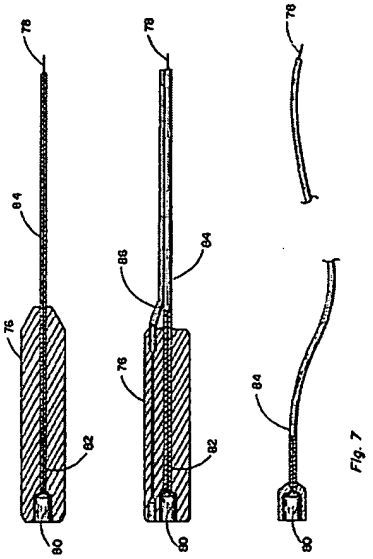


FIG. 9 illustrates another particularly preferred embodiment of the overall RF surgical tool compatible with and suitable for use in an operating room. As illustrated, the surgical unit comprises a cabinet **88** mounted on casters for ease of positioning the flexible arm **90** with inductive applicator **92** (solenoidal coil with variable capacitor) directly over a patient during surgery. To assist in positioning the coil within the applicator near the tissue to be surgically treated, a manual handle **94** is provided to rotate the solenoidal coil and raise/-lower or extend/retract the solenoidal coil along the flexible arm. The top of the cabinet **88** is conveniently used as a tray **96** with the plurality of interchangeable EFF probes **98** mounted to one side of the cabinet **88**. A conventional 120 volt (30 amps) grounded plug is used as the sole source of power for the RF generator, vacuum source and ancillary equipment mounted within the cabinet **88**.

During use of the equipment, the selected probe **98** is attached to grounded cable (with vacuum tube) **102** and held by the surgeon with the inductive applicator **92** positioned over the patient. The surgeon then uses foot pedal **104** to turn the RF field generator on and off as desired. The variable capacitor setting for adjustment for the inductive applicator is provided as a knob **106** near the manually positioned solenoidal coil. The rest of the electronic adjustments and meters are provided on the instrument panel of the cabinet and include typically, a power on/off switch **108**; a probe tuner know **110** with probe current meter **112**, an analog load **114** and analog tuner **116** adjustment knobs with RF power meter **118** and VSWR power meter **120**; along with a set of preset power level switches **122** for different probe types.

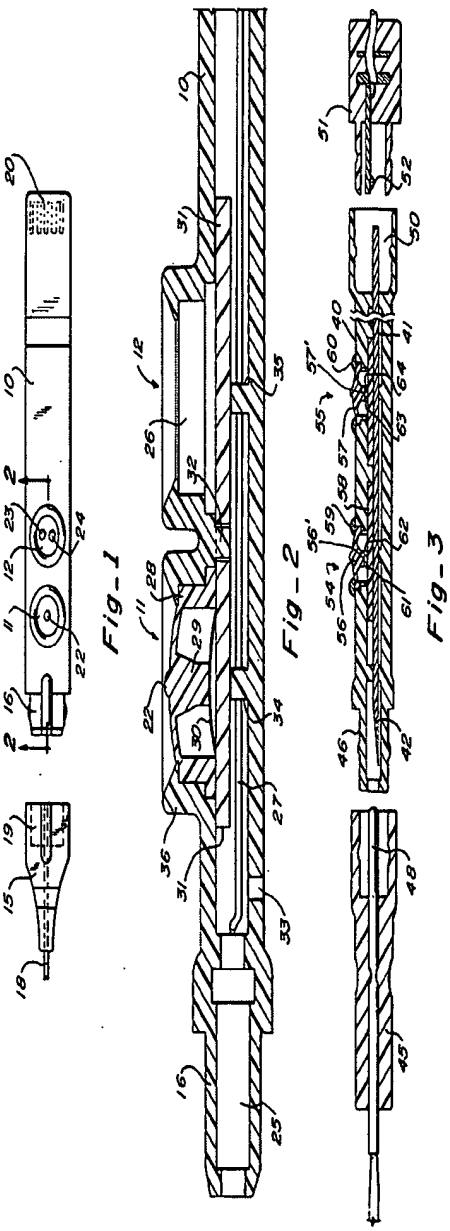


Fig-1 Fig-2 Fig-3

Esty Patent -- Column 3

The main housing 10 is arranged in a substantially flat elongated configuration. This housing more nearly approximates the flat handle feel of previous passive surgical instruments but still incorporates selector switches 11 and 12 near the end thereof so that the surgeon can select the desired electro-surgical procedure without movement of the instrument. At one end, replaceable chuck 15 is arranged so as to cooperate with the generally flat extension 16 from the body 10 in substantially the same manner as has been described in greater detail in the aforementioned cross-referenced application entitled Detachable Chuck For Electro-Surgical Instruments by J. M. Esty. As described in that application, chuck 15 has an exposed surgical electrode 18 which extends through the insulating body of chuck 15 so as to protrude within cavity 19. Thus the insulating shoulders of the chuck insert extension 16 on body 10 cooperates with chuck 15 so as to provide physical support as between the insulating sidewalls thereof while electrode 18 establishes a sliding contact for electrical current transmission therebetween but with this contact being substantially isolated from the environment of the surgery being performed. Although electrode 18 has been shown without the portion thereof which provides the passive and/or electro-surgical function such as a scalpel blade, wire loop or the like, it will be readily understood that any of these devices can be incorporated for the exposed portion of the electrode 18.

The broad general function performed by frame 10 with chuck 15 attached is to permit momentary switch actuations via switches 11 and 12 which are transmitted through a cable attached to socket 20 and then to an electro-surgical generator. The actuation of either of switches 11 or 12 in a typical application results in selection of a generally continuous high frequency signal as when switch 11 is actuated or a series of short RF pulses as when switch 12 is actuated. Whichever of these signals has been selected is returned from the signal generator through the cable (not shown) into socket 20 and thence through the housing 10 and into electrode 18 of chuck 15. In the particular example illustrated, selection of switch 11 produces a high frequency pulse for procedures such as tissue cutting with a wire loop at electrode 18 whereas selection of switch 12 effects a pulse selection into electrode 18 to provide cauterizing or coagulating functions.

THAT I have also reviewed the pictures, below, and associated description of the Anderson Patent No. 4,607,161 called FIBEROPTIC SWITCH SYSTEM. There is nothing in this patent that suggests anything about electro-surgical instrumentation.

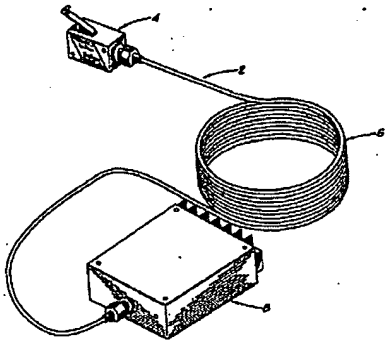
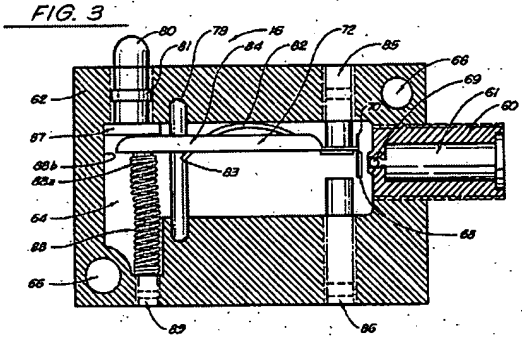


FIG. 1

FIG. 3



[57] **ABSTRACT**

A fiberoptic limit switch system comprising a light source, an optical beamsplitting arrangement, a switch, an optical fiber, a detector, and output circuitry. The light source is a light-emitting diode. The switch is responsive to external stimulus. The switch comprises a housing, a receptacle for receiving the optical fiber, and a reflective surface movable between two positions within the housing. The optical fiber extends from the light source to the switch. The detector is arranged so as to receive light from the optical fiber and transmit a signal relative to the light emission. The output circuitry is electrically connected to the detector.

Column 4

INVENTION

Referring to FIG. 1, there is shown at 2 a fiberoptic switch system for monitoring an external condition or stimuli, such as the position of a switch or moving part or some other physical condition which is desired to be monitored. Fiberoptic switching system 2 includes an optical switch 4 which detects changes in the monitored external condition, transmitting optical information or data signals via fiberoptic cable 6 to an electro-optic unit 8 where data from the switch 4 may be processed and stored or displayed.

. . .

FIGS. 3 and 4 illustrate the preferred embodiment of switch 16. The end of optical fiber 15 is coupled to

Column 5

switch 16 through connector 60. The exterior of connector 60 is designed so as to receive a male connector attached to the optical fiber. A housing arranged about the end of the optical fiber 15 is adapted to be received by orifice 61 of connector 60. When connected, the end of optical fiber 15 is received by connector 60 as seen in FIG. 5.

Switch 16 is formed by housing 62 having internal cavity 64. Housing 62 may be made of metals or plastics or other materials particularly suitable to the environment to which the switch will be subjected. Typically, the housing 62 is made of two sections connected together by glue, welds, bolts, or other means. As shown in FIGS. 3 and 4, these sections are connected together by screws fitted into areas 66.

THAT the three aforementioned patents do not discuss a resistively heated thermal cutting and coagulating surgical instrument that fits in the hand of a surgeon and the three patents all have components of the respective design that are *separate* features from the hand-held part of instrument itself and all three are also devoid of any suggestion of a switch mounted on the hand-held probe.

THAT the device described in Mr. Spears' patent application does not require a ground pad. This greatly simplifies the use of the device and minimizes the amount of set-up time and reduces the possibility of surgical errors cause by the lack of or faulty connection to a required ground pad.

That the combination the following three attributes of the device described in Mr. Spears' patent application: the use of the device without a ground pad; the electromagnetic field focusing (EFF) technique employed; and the switch-contact encased by the handheld probe housing; enable a more controlled and precise cutting than the devices described in the three aforementioned patents.

THAT I hereby declare that all statements made herein, in this 9-page DECLARATION, are of my own knowledge and that I have done my best to ensure they are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this patent application or any patent issuing to M. Spears thereon.

Signature: Bruce L Walcott

Typed name: Bruce L. Walcott, Ph.D.

Signed this: 19th day of the month of November in year 2003

The signing of this document was witnessed by (signature): Rosa C. Hicks

Typed name: Rosa C. Hicks